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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,503	08/17/2001	Tulin Morcol	37070/207071	6972

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,503	MORCOL ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *1-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 10-5-2004 are acknowledged. Claim 12 has been amended. Claims 1-12 are pending and claims 1-11 remain withdrawn from consideration. Claim 12 is currently under examination.

Objections Withdrawn

The objection to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code is withdrawn in light of the amendment thereto.

The objection to the disclosure because the status of the claimed priority documents on page 1 of the specification was not updated is withdrawn in light of the amendment thereto.

The objection to claim 12 for being dependent on non-elected claims (inventions) is withdrawn in light of the amendment thereto.

Claim Rejections Withdrawn

The rejection of claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn. Applicant's arguments have been fully considered and deemed persuasive.

The rejection of claim 12 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by reciting the phrase "therapeutic amount" is withdrawn. Applicant's arguments have been fully considered and deemed persuasive.

Claim Rejections Maintained

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claim 12 under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (WO 00/15194 IDS – 4/15/2002) in view of Corrigan et al. (WO 99/03451) is maintained for reasons of record.

The instant invention is drawn to a method of delivering a therapeutic amount of a therapeutic agent to a patient comprising orally delivering one or more particles wherein said particles comprise a calcium phosphate core, a therapeutic agent associated with said core and a casein layer that at least partially covers said core.

Applicant argues:

1. The particles of the present invention are quite different from those disclosed in Lee or Corrigan as the particles of the instant invention are produced by reconstructing casein micelles around therapeutic agent-loaded CAP particles creating a protective coat surrounding the CAP-therapeutic particles.

2. Neither Corrigan nor Lee discloses a particle with a casein layer at least partially covering a core comprising calcium phosphate.

3. The cited references, either alone or in combination, do not teach all the limitations of the instant invention.

Applicant's arguments have been fully considered and deemed non-persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention (Point 1), it is noted that the features upon which applicant relies (i.e., the casein micelles create a protective coat surrounding the CAP-therapeutic particles) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The instant claims merely require that a casein layer that at least partially covers said core.

With regard to Points 2 and 3, Lee et al. disclose the use of calcium phosphate particles as an adjuvant or delivery vehicle for therapeutic compounds or antigens (see abstract and pages 1-4). Lee et al. differs from instant invention in that they don't disclose the use of casein as a coating substance for the calcium phosphate particles. **Corrigan et al. disclose the use of casein in pharmaceutical compositions to reduce the irritating effects of the active ingredient**

(therapeutic compound) [see page 5 lines 10-14] and to provide controlled release pharmaceutical compositions for oral administration (see page 6, lines 4-6). Corrigan et al. further disclose that casein can be used in conjunction with multiple formulation "forms" including granules (i.e. particles) [see page 7, lines 20-32]. Consequently, it would have been obvious for one of skill in the art to use the casein disclosed by Corrigan et al. in conjunction with the calcium phosphate particles disclosed by Lee et al. in order to take advantage of the reduced gastrointestinal irritation and increased drug delivery associated with the use of casein. One of ordinary skill in the art would have had a high expectation of success since Corrigan et al. disclose that casein can be used with "granular formulations" and Lee et al. disclose that liposomes and polymers may be used to encapsulate their calcium phosphate particles wherein the liposomes serve as a delivery vehicle for the calcium phosphate particles (see page 20, line 30 to page 21, line 1). It should be noted that casein forms naturally forms microspheres in solution and hence is, by definition, a type of liposome/polymer as disclosed by Corrigan et al. Consequently, the combination of the cited references renders all the rejected claims obvious.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman
January 5, 2005

L. F. S.
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SUPERVISORY PATENT EXAMINER
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